

REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

Claims 1-20 are pending. Claims 11 and 20 stand withdrawn.

Applicants note with appreciation that the rejection under 35 U.S.C. § 102 over U.S. Patent No. 5,516,670 has been withdrawn.

Rejections Under 35 U.S.C. §102

Claims 1-10 and 12-19 are rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Zimmermann (U.S. Patent No. 4,971,910) ("Zimmerman").

Applicants submit that Zimmerman fails to recite every element of the presently claimed invention, as amended herein. To anticipate a claim, a single prior art reference must teach each and every element of the claimed invention. See M.P.E.P. § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

Independent claim 1 is directed to method for introduction or extraction of bioparticles into/from biological membrane-enveloped structures. The method comprises applying a magnetic alternating field to a sample comprising biological membrane-enveloped structures and magnetically susceptible particles, so that increase of the thermal and optionally kinetic energy of the magnetically susceptible particles causes the formation of pores in said biological membrane-enveloped structures. The pores allow the introduction or the extraction of bioparticles into or from the biological membrane-enveloped structures.

Zimmerman fails to recite each element of the presently claimed invention. Zimmerman describes a method to fuse cell membranes from two or more cells to create one cell. To bring the cells that are to be fused close enough together to achieve the fusion (and to circumvent the possibility that the cells repel each other) the cells are first doped with magnetic particles, and then subjected to a non-homogenous magnetic field. This magnetic field permeates the fusion space such that the doped cells collect close together. Thereafter, the cell membranes are fused

using one of three technologies (see abstract of Zimmerman): chemicals which cause disruptions in membranes, inactivated viruses which cause disruption in membranes, or short pulses of an electric field.

With regard to the electric field, Zimmerman recites that after collecting in the area of the highest field density of the magnetic field, the cells are briefly exposed to an external heterogeneous electric field with a frequency of from 5 kHz to 2 MHz and an intensity of from 10V/cm to 2000 V/cm (see column 4, lines 57-67). In such an electric field, the magnetic particles will not be heated at all, in contrast to the heat generated by the methods of the present invention. Such heat would be only generated in a *magnetic field*. An alternating magnetic field, as used in the present method, induces heat within the magnetic core of each particle due to both a rotation of the particle and due to rotation of the magnetic momentum within the particle. Both of these phenomenon result in heat losses. Which one of them that dominates in a given moment depends on the particle size, magnetic field frequency and particle coating.

Zimmerman fails to disclose such a magnetic field, but instead discloses an electric field, which does not cause the same phenomena within the particles. The electric field of Zimmerman does not create heat to increase the temperature of the particles, which would cause cell poration of the cells due to heating of the magnetic particles. Zimmerman does not inherently recite the present invention.

The use of an electric field to open pores is well established, usually defined as electroporation. This method is a completely separate method from that of the present invention and is not comparable to the methods of present claims 1-10 and 12-19. In the present invention, heating close to the cell or organelle membranes is important for the method. In contrast, heating of the cell sample causes problems when performing electroporation, and thus the skilled artisan would not want to heat the cell sample when using an electric field. Heating is avoided if the electrical pulses can be kept short. In fact, this is described by Zimmerman in the fusion process from column 4, line 68 to column 5, line 6 as follows: "Since before the alternating electrical field is applied the cells have already been collected by the action of the magnetic field, it takes only a brief activation of the electrical field to achieve the desired concatenation of the cells. Heating of the cell suspension and

thus of the cells is therefore largely avoided, while a row of cells is simultaneously produced."

Thus, Zimmerman fails to recite an alternating magnetic field which increases thermal energy in particles to create pores, but instead discloses an electric field where heating is not recommended. Thus, Applicants request that this rejection be withdrawn.

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Gordon (U.S. Patent No. 4,889,120) ("Gordon").

Gordon discloses a method to connect biological structures (anastomosis) by application of electromagnetic energy. The edges of the biological structures that are to be connected are doped with magnetic particles, either extracellular or intracellular. The edges are then brought close together, and the magnetic field is applied.

In Gordon, the magnetic particles heat all depths of the edges of the structures, but does not heat the whole structure. The heating is used to disrupt the edges of the structures, *i.e.*, to disrupt the edge tissue down in the two opposing edges while simultaneously pull them close together in order to weld the edges together. After the heating process, the two structures are meant to heal and form a connection. The procedure is done quickly. Additional sutures may be needed during healing, so that the two structures grow together tightly.

Applicants submit that Gordon does not inherently disclose the poration of cell membranes. The purpose of the heating as recited in Gordon is to disrupt several cells permanently, in order to create a surface open for healing the two edges together. The heating of the magnetic particles recited in Gordon has to be severe and of sufficient magnitude to disrupt the tissue in the course of the welding process. If such a heating process were applied to the present method, it would result in cell death, and would not open temporary pores for the importation and exportation of molecules across the cell membrane. Applicants again note that Gordon only discloses heating the edges and not the entire structure as in present claim 1. Heating the entire cell using the method of Gordon would kill the cell, defeating the purpose of the method of claim 1, instead of opening pores.

Further, the purpose of the Gordon patent is not to allow the introduction or extraction of bioparticles into/from said biological membrane-enveloped structures, but rather, as stated above, connecting biological structures as is needed for instance in vascular surgery, gastrointestinal tract surgery, and urological surgery, (see column 1, lines 18-22).

In view of the above it is still considered that the present invention is patentable over the prior art and the invention fulfils the criteria required for grant.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, Notice of Allowance is respectfully requested.


In the event that there are any questions relating to this Amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

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(INCLUDING THE ATTORNEYS FROM BURNS DOANE SWECKER & MATHIS)

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